Bio-Path Holdings Provides Clinical Update and 2019 Business Outlook

HOUSTON – December 27, 2018 – Bio-Path Holdings, Inc., (NASDAQ: BPTH), a biotechnology company leveraging its proprietary DNAbilize® antisense RNAi nanoparticle technology to develop a portfolio of targeted nucleic acid cancer drugs, today provides an update from several clinical development programs and a 2019 business overview.

"Over the last year, we made solid progress across our growing development pipeline, highlighted by positive interim data from our Phase 2 study of prexigebersen in de novo acute myeloid leukemia (AML) patients," stated Peter H. Nielsen, chief executive officer of Bio-Path Holdings. "We enter 2019 focused and optimistic about our prospects for the clinical advancement of our pipeline of RNAi nanoparticle drugs in patients suffering from a variety of cancers of unmet medical need."

Phase 2 Study of Prexigebersen in De Novo AML Patients

In August 2018, Bio-Path announced first patient dosed in Stage 2 of the open-label Phase 2 study evaluating the efficacy and safety of prexigebersen (an antisense RNAi nanoparticle against Grb2 protein) in combination with LDAC and a second cohort of prexigebersen and decitabine, both therapeutic regimens well established in treatment of acute myeloid leukemia (AML) patients who cannot or elect not to be treated with more intensive chemotherapy. The primary objective of the study is to determine whether these combinations with prexigebersen provide greater efficacy than what would be expected with low-dose cytarabine (LDAC) or decitabine alone in this de novo patient population. In 2019, Bio-Path expects to open three trial sites in the EU, which Bio-Path expects will accelerate patient enrollment.

As previously announced, a planned interim analysis of Stage 1 of the study was performed on 17 evaluable patients, with four patients achieving complete responses (24%) and four patients achieving stable disease, including one patient achieving a morphologic leukemia free state and one patient who showed significantly reduced bone marrow blasts. In total, 47% of the evaluable patients showed some form of response, including stable disease, to the prexigebersen and LDAC combination treatment.

Efficacy data are encouraging in this challenging population in which the majority of patients had secondary AML or adverse-risk AML, and compares favorably to the reported CR (complete remission), CRp (complete remission with incomplete platelet recovery), and CRi (complete remission with incomplete hematologic recovery) rate with LDAC alone of 7-13%[1].

Plans for a pivotal trial are expected to be discussed with the FDA if these results exceed expectations for current standard-of-care therapy.

Phase 2a Study of Prexigebersen in Accelerated and Blast Phase CML Patients

Bio-Path plans to continue enrolling patients in 2019 in a Phase 2a clinical study of prexigebersen in combination with the frontline therapy, dasatinib, for the treatment of chronic myeloid leukemia (CML) in accelerated and blast phase patients. For 2019, additional sites are planned to be added and enrollment planned to be opened across both phases of the disease, including imatinib-resistant chronic phase patients. The trial is currently being conducted at The University of Texas MD Anderson Cancer Center as a potential salvage therapy for accelerated and blast phase CML patients.

Two cohorts of three evaluable patients each are expected to be enrolled to evaluate two doses (60 mg/m2 and 90 mg/m2) of prexigebersen in combination with dasatinib.

Phase 1 Study of Prexigebersen in Patients with Advanced Solid Tumors

In 2019, Bio-Path intends to initiate a Phase 1 clinical trial of prexigebersen in patients with advanced solid tumors, including ovarian and uterine, pancreatic and hormone refractory breast cancer. This trial is expected to be conducted at several leading cancer centers and is planned to evaluate the safety of prexigebersen in combination with standard-of-care for each tumor type.

Phase 1 Study of BP1002 in Refractory or Relapsed Lymphoma Patients

Bio-Path expects to initiate a Phase 1 clinical trial of BP1002, an antisense RNAi nanoparticle targeting the Bcl-2 protein, in refractory or relapsed lymphoma and chronic lymphocytic leukemia (CLL) patients in 2019. The clinical trial is expected to be conducted at several premier cancer centers and is planned to evaluate the safety of BP1002 in several dose escalating cohorts to determine a maximum tolerated dose.

Preclinical Development of BP1003

The Company continues to advance its third investigation drug candidate, BP1003, for the treatment of advanced solid tumors, including pancreatic cancer. BP1003 is an antisense RNAi nanoparticle targeting the Stat3 protein. Bio-Path intends to initiate several Investigational New Drug application (IND) enabling studies for BP1003 in 2019.

[1] Heiblig, Mediterr J Hematol 2016; Kantarjian, J Clin Oncol 2012; Dohner, Blood 2014.

About Bio-Path Holdings, Inc.

Bio-Path is a biotechnology company developing DNAbilize®, a novel technology that has yielded a pipeline of RNAi nanoparticle drugs that can be administered with a simple intravenous transfusion. Bio-Path's lead product candidate, prexigebersen (BP1001, targeting the Grb2 protein), is in a Phase 2 study for blood cancers and in preclinical studies for solid tumors. This is followed by BP1002, targeting the Bcl2 protein, which the company anticipates entering into clinical studies where it will be evaluated in lymphoma and solid tumors.

For more information, please visit the Company's website at http://www.biopathholdings.com.

Forward-Looking Statements

This press release contains forward-looking statements that are made pursuant to the safe harbor provisions of the federal securities laws. These statements are based on management's current expectations and accordingly are subject to uncertainty and changes in circumstances. Any express or implied statements contained in this press release that are not statements of historical fact may be deemed to be forward-looking statements. Any statements that are not historical facts contained in this release are forward-looking statements that involve risks and uncertainties, including Bio-Path's ability to raise needed additional capital on a timely basis in order for it to continue its operations, have success in the clinical development of its technologies, the timing of enrollment and release of data in such clinical studies and the accuracy of such data, limited patient populations of early stage clinical studies and the possibility that results from later stage clinical trials with much larger patient populations may not be consistent with earlier stage clinical trials, and such other risks which are identified in Bio-Path's most recent Annual Report on Form 10- K, in any subsequent quarterly reports on Form 10-Q and in other reports that Bio-Path files with the Securities and Exchange Commission from time to time. These documents are available on request from Bio-Path Holdings or at www.sec.gov. Bio-Path disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

# # #

Contact Information:

Investors

Will O'Connor
Stern Investor Relations
212-362-1200
will@sternir.com

Doug Morris
Investor Relations
Bio-Path Holdings, Inc.
832-742-1369